

5 510(k) Summary

APR 28 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment Siemens Medical Solutions, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Registration Number 2240869

Manufacturer Siemens AG.
Henkestrasse 127
D-91052 Erlangen, Germany

Registration Number 8010024

Contact Person Judith Campbell
Regulatory Technical Specialist.
51 Valley Stream Parkway
Malvern, PA 19355
Phone: (610) 761-1860
Fax: (610) 448-1787

Device Name

Trade name syngo BreVis
Classification Name Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel: Radiology
Regulation number: 21 CFR § 892.1000
Device Class: II
Product Code: LNH

Summary Device Description

syngo BreVis is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. syngo BreVis supports evaluation of dynamic MR data. Depending on the region of interest, contrast agents may or may not be used.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use

syngo BreVis is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. *syngo BreVis* supports evaluation of dynamic MR data. Depending on the region of interest, contrast agents may or may not be used.

syngo BreVis automatically registers serial patient motion to minimize the impact of patient motion and visualizes different enhancement characteristics in those areas that are within the scope of the indications for use of MRI FDA approved contrast agents (parametric image maps).

Furthermore, it performs other user-defined post-processing functions such as image subtractions, multiplanar reformats and maximum intensity projections.

The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. *syngo BreVis* can also be used to provide measurements of the diameters, areas and volumes.

Furthermore *syngo BreVis* can evaluate the uptake characteristics of segmented tissues that are within the scope of the indications for use of MRI FDA approved contrast agents.

syngo BreVis includes software to support the use of interventional coils and MR stereotactic localization devices to perform MR-guided interventional procedures (*syngo BreVis Biopsy*). Using information from MR images regarding the coordinates of a user-specified region of interest and fiducial coordinates, *syngo BreVis* provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion.

syngo BreVis is optimized for viewing breast MR studies, and it also displays images from a number of other imaging modalities, like digitized mammographic images. The images by other imaging modalities displayed with *syngo BreVis* must not be used for primary diagnostic interpretation.

syngo BreVis also includes the option to add annotations based on the American College of Radiology's BI-RADS (Breast Imaging and Data System).

When interpreted by a skilled physician, *syngo BreVis* provides information that may be useful in diagnosis. Patient management decisions should not be made based solely on the results of *syngo BreVis* analysis.

Performance Standards

None established under Section 514 the Food, Drug, and Cosmetic Act.

Substantial Equivalence

syngo BreVis is substantially equivalent to the following cleared medical devices:

Predicate Software Name	FDA Clearance Number	FDA Clearance Date
CADstream V4.0	K043216	Jan 6, 2005
DynaCAD V1.0	K041286	July 21, 2004

General Safety and Effectiveness Concerns:

The introduction of syngo BreVis has no significant concerns of safety and efficacy.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via Risk Analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

syngo BreVis will conform to the measurement of safety and performance parameters to the international IEC and ISO standards, where applicable.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2009

Ms. Judith Campbell
Regulatory Technical Specialist
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K090038

Trade/Device Name: *syngo BreVis*
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 20, 2009
Received: March 23, 2009

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices; good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

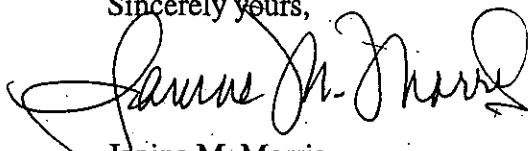
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known) K090C38

Indications for Use:

syngo BreVis is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. *syngo* BreVis supports evaluation of dynamic MR data. Depending on the region of interest, contrast agents may or may not be used.

syngo BreVis automatically registers serial patient motion to minimize the impact of patient motion and visualizes different enhancement characteristics in those areas that are within the scope of the indications for use of MRI FDA approved contrast agents (parametric image maps).

Furthermore, it performs other user-defined post-processing functions such as image subtractions, multiplanar reformats and maximum intensity projections.

The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. *syngo* BreVis can also be used to provide measurements of the diameters, areas and volumes.

Furthermore *syngo* BreVis can evaluate the uptake characteristics of segmented tissues that are within the scope of the indications for use of MRI FDA approved contrast agents.

syngo BreVis includes software to support the use of interventional coils and MR stereotactic localization devices to perform MR-guided interventional procedures (*syngo* BreVis Biopsy). Using information from MR images regarding the coordinates of a user-specified region of interest and fiducial coordinates, *syngo* BreVis provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion.

syngo BreVis is optimized for viewing breast MR studies, and it also displays images from a number of other imaging modalities, like digitized mammographic images. The images by other imaging modalities displayed with *syngo* BreVis must not be used for primary diagnostic interpretation.

syngo BreVis also includes the option to add annotations based on the American College of Radiology's BI-RADS (Breast Imaging and Data System).

Section 4:

Indications for Use Statement

When interpreted by a skilled physician, *syngo BreVis* provides information that may be useful in diagnosis. Patient management decisions should not be made based solely on the results of *syngo BreVis* analysis.

(please do not write below this line- continue on another page if needed)

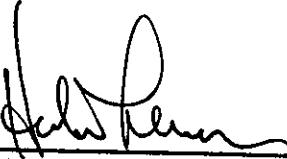
Concurrence of CDRH, Office of Device Evaluation

Prescription Use X

OR

Over-The-Counter Use _____

Page of



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090038